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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,751	12/21/2000	Mark N. Hochman	3486-018	1104
22440	7590	06/29/2004	EXAMINER	
GOTTLIEB RACKMAN & REISMAN PC 270 MADISON AVENUE 8TH FLOOR NEW YORK, NY 100160601			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/745,751		HOCHMAN, MARK N.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Michael J Hayes		3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 2, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/07/04 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by BROWN (U.S. Patent No. 3,244,172). Brown discloses that it is well known in the art to turn or twist a needle of a syringe while inserting it through tissue in methods of injecting. (1:15-23).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 6, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over KUHLE (US Patent No. 5,938,635) in view of Violante (US Patent No. 6106473). Kuhle discloses a method of advancing a needle while rotating to reduce deflection of the needle. Kuhle teaches a rotation of 360 degrees to balance forces, or alternatively several rotations of 180 degrees while advancing the needle. Kuhle discloses his method with a biopsy needle and does not discuss injecting a drug. Violante teaches the importance in the medical arts of placing needles and other medical devices for biopsy and drug delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Violante in the method of Kuhle to recognize the desirability for accurately placing biopsy and drug delivery needles and the established equivalence between placing needles used for biopsy and placing drug delivery needles in identifiable locations. Re claim 6 use of an advance rate of 2-4 mm/sec would be obvious to one of ordinary skill in the art as a design choice because Applicant has not stated that this advance rate serves any particular purpose or solves any stated problem and it appears that other advance rates would function equally as well. Applicant has not established any criticality to this advance rate.

Claims 3, 4, 8, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over KUHLE and VIOLANTE as applied to claims 1 and 7 above, and further in view of Garnier (US Patent No. 4381777). Kuhle and Violante disclose the claimed invention except for rotating the needle in one direction, then the opposite direction. Violante teaches one directional and also bi-directional rotation (1:22-34). It would have been obvious to one of ordinary skill in the art at

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the time of the invention to use the teachings of Violante in the method of Kuhle and Garnier in order to avoid special precautions (i.e., achieve a simpler method) and to avoid injury or breakage.

***Declaration Under 37 1.132***

The declaration under 37 CFR 1.132 filed 6/07/04 is insufficient to overcome the rejection of claims 1 and 7 based upon Brown as set forth in the last Office action because: the recited claims 1 and 7 read on the disclosure in Brown. Declarant established expertise in anesthesiology and presented statements that he had never heard of the claimed process. Applicant's claims 1 and 7 have a greater scope than anesthesiology. The declaration does not present sufficient evidence to read the prior art in a different light than what it plainly states.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
24 June 2004



**MICHAEL J. HAYES  
PRIMARY EXAMINER**